

DNB

3.31.99
4.5.99
Certifier C. WMS-DAY

@11:57

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 26

[Docket No. 98N-0185]

RIN 0910-ZA11

Mutual Recognition of Pharmaceutical Good Manufacturing Practice Inspection Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports Between the United States and the European Community; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of November 6, 1998 (63 FR 60122). The document amended FDA's regulations under an international agreement between the United States and the European Community. FDA took this action to enhance its ability to ensure the safety and effectiveness of pharmaceuticals and medical devices through more efficient utilization of its regulatory resources. The document was published with some inadvertent errors. This document corrects those errors.

EFFECTIVE DATE: March 31, 1999.

FOR FURTHER INFORMATION CONTACT: Merton V. Smith, Office of International Affairs (HFG-1), Office of External Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0910, or e-mail "MSmith@oc.fda.gov".

OC9925

NCR 1

SUPPLEMENTARY INFORMATION: In FR Doc. 98-29609, appearing on page 60122, in the **Federal Register** of Friday, November 6, 1998, the following corrections are made:

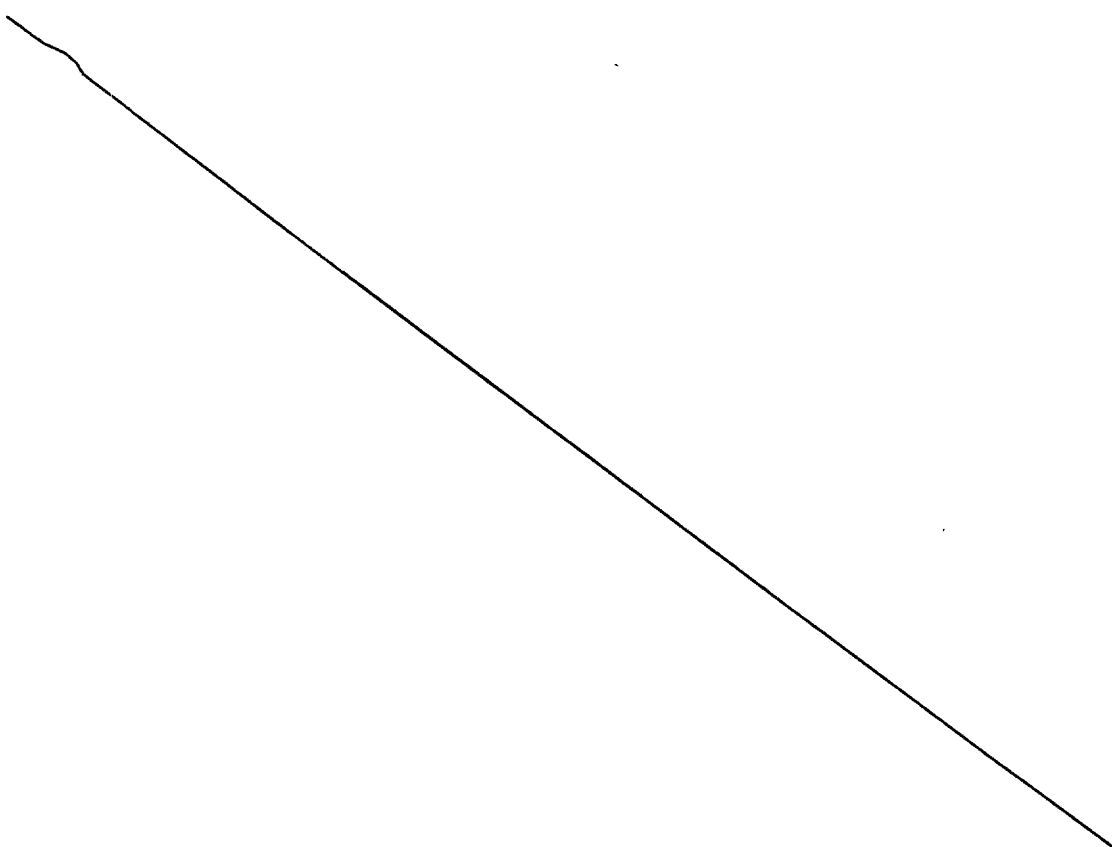
1. In the preamble, on page 60137, in the third column, in the fifth paragraph, in the third line, after “to the following:”, “that only” is removed.

§ 26.1 [Corrected]

2. On page 60142, in the first column, in § 26.1(c), in the fourth line, “that only” is removed.

§ 26.50 [Corrected]

3. On page 60153, in Appendix B of subpart B in § 26.50, in Table 2, in the first column, under the subheading “Clinical Thermometers:”, the third entry beginning with “AN 868.5925 * * *” is removed; in that same table, under the subheading “Hypodermic Needles and Syringes (except anti-stick and self-destruct):”, the third entry beginning with “OR 888.3020 * * * is



removed; and in that same table, the subheading “External Fixators (except devices with no external components):” and the two entries that follow are removed.

Dated: March 30, 1999

A handwritten signature in cursive script, reading "William K. Hubbard", written over a horizontal line.

William K. Hubbard
Acting Deputy Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL